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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,302

10/21/2005

Stanley Shepherd

2002.034US/AH06008US01

9816

31846

7590

07/22/2010

Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

07/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

Office Action Summary	Application No. 10/534,302	Applicant(s) SHEPHERD, STANLEY	
	Examiner SHANON A. FOLEY	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 1, 2010 has been considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 4-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ligon et al. (US 5,639,949) and Colin et al. (WO 00/61068, previously cited) for reasons of record.

Applicant argues the use of hindsight reasoning to piece together the rejections. Specifically, Ligon discloses antipathogenic substances which are those having a harmful effect on plant pathogens. Applicant asserts that nothing in Ligon teaches water soluble macrocyclic lactones and benzimidazoles could be used in an aqueous formulation for topical application to an animal.

In response, it is acknowledged that Ligon does not teach that the formulation as veterinarily acceptable in the Office Action, see page 3, lines 8-9 of Office Action. Colin et al. was relied upon to teach formulations which are acceptable for use as a veterinary formulation. As the formulations of Ligon and Colin both teach macrocyclic lactone, benzimidazolone and polyethylene glycol, it would have been obvious to the skilled artisan to use the composition of

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Ligon for veterinary acceptable applications. Furthermore, Ligon teaches that antipathogenic substances are used to control pathogens in heterologous hosts, see column 17, lines 28-31.

Applicant further argues that although Colin teaches a liquid, a liquid is clearly not synonymous with aqueous. The formulation of Colin comprises aromatic solvents which are liquid, but Colin does not teach or suggest the inclusion of water in any formulation. Therefore, Colin cannot teach or suggest an aqueous micellar formulation as claimed.

In response, the formulations of Colin are liquid solutions, and used for pour on applications. Though the pour on solutions of Colin do not expressly teach aqueous formulations containing water, Colin does teach liquid solutions are used for the formulations. Furthermore, water based formulations are already taught in Ligon. Colin is relied upon to teach the administration of formulations comprising the specific macrocyclic lactone, avermectin for veterinary purposes.

Applicant further argues that Colin teaches away from an aqueous solution as Colin teaches that known anthelmintic formulations are usually suspensions because of the water insoluble nature of triclabendazole, see Colin p. 1 lines 23-25.

In response, the Examiner respectfully submits that Colin merely teaches that the formulations are developed with solvents which have good affinity for penetrating the skin including benzyl alcohol. Benzyl alcohol is soluble in water. Colin does not teach that aqueous solutions are not used in the formulations. Furthermore, the aqueous formulations are already taught in Ligon. It is the combined teachings of Ligon and Colin that arrive at the aqueous formulation. The Examiner relied upon Colin to teach that the formulations of Ligon would

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necessarily be suitable for veterinary use due to the common ingredients including macrocyclic lactones, benzimidazole and polyethylene glycol.

Applicant refutes that the concentrations of the active ingredients are obvious since the solubility of the active ingredients and the dose required would not have been reasonably predicted to be sufficient for the control of internal parasites.

Applicant's arguments have been fully considered, but are found unpersuasive since Colin specifically teach sufficient control of liver flukes in a pour-on composition and the preferred solvent for the active ingredients to penetrate the skin is benzyl alcohol, which is soluble in water.

Claims 3, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ligon et al. and Colin et al. as applied to claims 1, 2 and 4-21 above, and further in view of Domb (US 7,026,290) and Egelrud et al. (US 5,981,256).

While claim "3" was inadvertently omitted from the grounds of rejection above in the previous correspondence, its omission was clearly an inadvertent typo since the limitations of the claim, requiring "polyoxyethylene (20) sorbitan monolaurate" and motivations for using this compound as a surfactant are discussed on pages 5-6 of the Office Action.

Applicant argues that the combination of Domb and Egelrud are insufficient to overcome the deficiencies of Colin and Ligon. However, arguments regarding deficiencies are found unpersuasive and the rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
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